



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2021-0067, NIOSH-342]

**Draft - Approaches to Developing Occupational Exposure
Limits or Bands for Engineered Nanomaterials: User Guide
and Technical Report**

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) .

ACTION: Request for comment.

SUMMARY: NIOSH announces the availability of a draft technical report entitled *Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials: User Guide and Technical Report* now available for public comment. To view the notice and related materials, visit <https://www.regulations.gov> and enter CDC-2021-0067 in the search field and click "Search."

DATES: Electronic or written comments must be received by **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]** .

ADDRESSES: You may submit comments, identified by CDC-2021-0067 and docket number NIOSH-342, by any of the following methods:

- *Federal eRulemaking Portal:*

<https://www.regulations.gov> Follow the instructions for submitting comments.

- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2021-0067; NIOSH-342]. All relevant comments received will be posted without change to

<https://www.regulations.gov>, including any personal information provided. All electronic comments should be formatted as Microsoft Word. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226-1998.

FOR FURTHER INFORMATION CONTACT: Nathan Drew, National Institute for Occupational Safety and Health, Emerging Technologies Branch, 1090 Tusculum Avenue, MS C-14, Cincinnati, OH 45226, telephone (513) 533-8352 (not a toll free number).

SUPPLEMENTARY INFORMATION: On December 17, 2019, the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention announced in the **Federal Register** [84 FR 68935] plans to evaluate the scientific data on engineered nanomaterials for the development of categorical occupational exposure limits. The draft NIOSH technical report describing approaches to evaluating these scientific data is now available for public comment, *Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials: User Guide and Technical Report*.

Background: Most chemical substances, including engineered nanomaterials, do not have specific occupational exposure limits. Alternative methods are needed to assess the potential occupational safety and health hazards of engineered nanomaterials. Categorical occupational exposure limits are one approach to estimating exposure concentrations for groups of materials with similar toxicological effects and/or physicochemical properties. Occupational exposure banding is another approach to protect worker health by assigning chemical substances into specific categories or "bands" based on their associated health outcomes and on potency considerations. These bands correspond to a range of airborne exposure concentrations to inform risk management decisions for substances that do not have occupational exposure limits. NIOSH has proposed an

evidence-based approach to evaluate the scientific information available in order to derive occupational exposure limits, or bands, for engineered nanomaterials. This proposed approach is described in the draft NIOSH technical report available for public comment, *Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials: User Guide and Technical Report*. This draft report contains two main parts: (I) User Guide and (II) full Technical Report and Appendixes.

The purpose of the public comment period is to obtain comments on the draft report. Comments are being sought from individuals including scientists and representatives from various government agencies, industry, labor, and other stakeholders, and also the public. If there are errors of fact, unsubstantiated claims, evidence of careless experimental work, inclusion of too much information already in the literature, or statements that are inaccurate, please note such in your review comments.

The authors ask that special emphasis be placed on technical review of the following issues:

1. Does the draft document adequately describe the process for gathering and evaluating the information available on occupational exposure limits or bands for engineered nanomaterials?

2. Does the draft document adequately describe the development of a framework for categorizing engineered nanomaterials by potential occupational health hazard from inhalation exposure?
3. Are the clustering and classification modeling methodologies reasonable for these data?
4. Is a revision to current occupational exposure banding guidance needed to incorporate a band F?
5. How useful and practical is the approach described in both the user guide and full technical report for deriving categorical occupational exposure limits, and what are the opportunities for improvement?
6. Are the current searches and collection of scientific data sufficient, and are there additional opportunities for obtaining data that were not included?
7. Would the methods used in the report also be appropriate for a future comprehensive dataset of experimental, toxicological, and physicochemical information for engineered nanomaterials?
8. Are there additional comments that you would like to provide?

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

